

## **EXHIBIT B**

**BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION**

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**IN RE GADOLINIUM CONTRAST AGENT LITIGATION**

**MDL Docket No. 1909**

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**RESPONSE OF DEFENDANTS**

**BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER HEALTHCARE LLC,  
BAYER CORPORATION AND BAYER PHARMACEUTICALS CORPORATION  
TO PLAINTIFFS' MOTION FOR TRANSFER AND CONSOLIDATION  
PURSUANT TO 28 U.S.C. § 1407**

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## INTRODUCTION

The products liability cases which are the subject of this motion to transfer involve four different defendants, not all of which are parties to every case. The cases allege use of different products at different times. Plaintiffs' motion seeks the transfer of cases involving alleged injuries arising out of the use of gadolinium-based contrast agents ("GBCAs") for magnetic resonance imaging ("MRI") to the Southern District of Ohio for coordinated and consolidated pretrial proceedings pursuant to 28 U.S.C. §1407. Defendants Bayer HealthCare Pharmaceuticals Inc. (the marketer of Magnevist®), Bayer HealthCare LLC, Bayer Corporation, and Bayer Pharmaceuticals Corporation (hereinafter "Bayer Defendants") do not oppose Plaintiffs' motion for transfer and consolidation. However, the Bayer Defendants submit that, if Plaintiffs' motion for transfer and consolidation is granted, the Northern District of Ohio is better suited to act as the MDL transferee court to oversee and resolve pretrial matters in this complex products liability litigation.

The Northern District of Ohio is a district in which four GBCA cases have been filed. Those GBCA cases are now consolidated before the Honorable Dan Aaron Polster, who has already held one case management conference in the *Rockwell* case. Judge Polster is a seasoned judge and highly capable of efficiently handling a complex products liability MDL litigation. Indeed, his district's Chief Judge sent a letter *sua sponte* to the Judicial Panel on Multidistrict Litigation ("JPML") requesting and endorsing Judge Polster as the transferee judge for this litigation. Further, the Northern District of Ohio has the judicial and court resources to handle this litigation, is geographically central to the parties and easily accessible. For all of these reasons, the Northern District of Ohio is the preferable forum to be the transferee court for this MDL.

## **BACKGROUND**

### **The Products**

The Bayer product, Magnevist®, is an injectable GBCA designed to enhance the diagnostic quality in magnetic resonance imaging (“MRI”). Magnevist® utilizes the strong paramagnetic properties of the earth metal gadolinium to facilitate the visualization of abnormal lesions throughout most of the body. Magnevist® was the first GBCA approved by the FDA in 1988. FDA has also approved four other GBCAs: Omniscan®, marketed by GE Healthcare and related companies (“GE defendants”); OptiMARK®, marketed by Mallinckrodt, Inc. and Tyco Healthcare Group LP (“Mallinckrodt defendants”); and ProHance® and MultiHance®, marketed by Bracco Diagnostic Inc. (“Bracco”).

Plaintiffs in these cases all seek recovery for personal injuries allegedly caused by their exposure to GBCAs. The injury at issue is a disease called nephrogenic systemic fibrosis (“NSF”). NSF was first described in the medical literature in 2000 as a new disease causing progressive thickening of the skin, dermatological lesions, contractures around joints and other signs and symptoms. Although the causes of NSF remain to be determined, the first suggestion in the medical literature that GBCAs might play a role in NSF was in January 2006 – over 18 years after Magnevist® was first approved by FDA and after 70 million administrations of Magnevist® worldwide. As with all prescription drugs, the Magnevist® labeling has been updated as additional information and post-marketing experience has been observed. The Bayer Defendants have several meritorious defenses and intend to vigorously defend these cases.

### **The Litigation**

Various plaintiffs have filed at least thirty-eight (38) products liability cases against GBCA defendants in eighteen (18) different federal district courts across the country. The Bayer

Defendants have been served in nine federal cases to date. Most of the cases allege that the defendants knew or should have known of the risk of NSF from using GBCA during MRIs of patients with renal disease, that the defendants should have warned of that risk of NSF, and that the risk of NSF made the GBCAs defective. Most of the district courts have only one or two cases, with the exception of the Southern District of Ohio, which has five cases, and the Northern District of Ohio, which has four cases. The Southern District cases each have only one set of GBCA defendants: only the GE defendants in four of the cases, and only the Bayer defendants in the fifth case (*Frazier*). The Northern District has one case involving both Bayer and GE defendants (*Rockwell*), two cases with only the GE defendants, and one case with only the Tyco defendants. The Southern District cases have all been transferred by local rule to the Honorable Algenon Marbley in Columbus, while the Northern District cases have all been transferred by local rule to the Honorable Dan Aaron Polster in Cleveland.

Very limited discovery has occurred in any of the cases. Certain Rule 26 disclosures have been made, but no documents have been produced and no depositions have been taken in any GBCA cases.

ARGUMENT

**THE MOST APPROPRIATE TRANSFEREE FORUM FOR THIS COMPLEX LITIGATION IS THE NORTHERN DISTRICT OF OHIO**

Given the pendency of multiple GBCA cases across the country in early stages of discovery, the Bayer Defendants understand that the JPML may likely grant Plaintiffs' motion for transfer and consolidation. However, the Bayer Defendants respectfully submit that, if Plaintiffs' motion is granted, the GBCA cases should be transferred to the Northern District of Ohio.

The selection of an appropriate MDL transferee forum depends greatly on the specific facts and circumstances of the litigation being considered for transfer and consolidation, and involves a "balancing test based on the nuances of a particular litigation" which considers several factors. *See Robert A. Cahn, A Look at the Judicial Panel on Multidistrict Litigation, 72 F.R.D. 211, 214 (1977).* While the venue where the majority of cases are pending, as pointed out by Plaintiffs, is a consideration, many other considerations are important, such as (1) the experience of the transferee judge with the litigation; (2) the experience of the transferee judge with MDL litigation; (3) a centrally located forum for litigation otherwise national in scope; (4) the backlog of a court's civil docket; and (5) the preference of the parties. The authors of the Manual for Complex Litigation concur:

The Panel uses no single factor to select the transferee district, but the Panel does consider where the largest number of cases is pending, where discovery has occurred, where cases have progressed furthest, the site of the occurrence of the common facts, where the cost and inconvenience will be minimized, and the experience, skill, and caseloads of available judges. Based on these factors, the Panel will designate a judge (on rare occasions, two judges) to whom the cases are then transferred for pretrial proceedings.

Manual for Complex Litigation, Fourth, § 20.131, p. 221.

**I. The Just and Efficient Conduct of the Actions Favor Transferring the Cases to the Northern District of Ohio**

The just and efficient conduct of the GBCA actions favors transferring the cases to the Northern District of Ohio. The Northern District of Ohio has a very capable bench with experience in managing pharmaceutical and medical device MDL litigations, the district has the resources necessary for the efficient conduct of this MDL, and the district is easily accessible and geographically central to the parties.

**A. The Northern District of Ohio Has An Experienced Bench Capable of Managing This Litigation Efficiently.**

The Northern District of Ohio is the most appropriate forum for transfer because the judges of this district have considerable experience in managing pharmaceutical and medical device products liability MDL litigations. Further, the judge currently assigned the four GBCA cases in the district, the Honorable Dan Aaron Polster, has the experience necessary to handle this litigation, and the support of his district's Chief Judge to be the transferee judge.

Judicial experience is an important factor that the JPML has considered in choosing a venue for an MDL case. In determining which district to transfer actions related to the weight loss drug Meridia, the JPML found that given the geographic dispersal of the cases, no district stood out as the geographic focal point for such a nationwide litigation. Thus, the JPML turned its attention to finding a "transferee judge with the time and experience to steer this complex litigation on a prudent course." In re Meridia Products Liability Litigation, 217 F. Supp. 2d 1377, 1378 (J.P.M.L. 2002).

The judges of the Northern District of Ohio have considerable experience managing pharmaceutical and medical device products liability MDL litigations, such as: the ORTHO EVRA® Products Liability Litigation MDL, the Meridia Products Liability Litigation MDL and

Sulzer Orthopedics Hip and Knee Prosthesis Products Liability Litigation MDL. The Northern District of Ohio judge who is currently assigned its four GBCA cases, Judge Polster, is a very capable jurist with the temperament, energy and interest to handle a large products liability MDL. Judge Polster is an experienced federal judge who has authored opinions resolving Daubert, class certification and preemption motions, which are issues likely to surface in this litigation. Judge Polster has the time and experience to steer the GBCA litigation on a prudent course. Additionally, the Chief Judge of the Northern District of Ohio, the Honorable James G. Carr, has indicated to the JPML in correspondence that he supports the transfer of the GBCA cases to his district and recommended Judge Polster as the transferee judge. See Exhibit 1, November 6, 2007 Letter of the Hon. James G. Carr, the Chief Judge of the Northern District of Ohio, to the Hon. John G. Heyburn II of the Western District of Kentucky and Chairman of the Judicial Panel on Multidistrict Litigation. In his letter to Judge Heyburn, Judge Carr noted that the judges in his district have “developed considerable experience with MDL litigation.” *Id.* In recommending Judge Polster specifically, Judge Carr pointed out that “his case management skills are excellent, and he is willing to take on this assignment.” *Id.* The strong support of the Chief Judge of the Northern District of Ohio is another factor weighing in favor of transferring the GBCA cases to Judge Polster.

**B. The Northern District of Ohio Has the Resources this Litigation Will Likely Require.**

Another factor taken into account by the Panel, and which favors the Northern District of Ohio, are the resources available in the district and the relative congestion of the district’s docket. *See, e.g., In re GMAC Insurance Management Corp. Overtime Pay Litigation*, 342 F. Supp. 2d 1357, 1357 (J.P.M.L. 2004) (finding that the Middle District of Florida was an appropriate forum because it had “the resources available to manage this litigation”); *In re*

Musha Cay Litigation, 330 F. Supp. 2d 1364, 1364 (J.P.M.L. 2004) (finding that the District of Nevada was an appropriate forum where the district had the resources the docket was likely to require); In re Baycol Products Liability Litigation, 2001 WL 34134820 at \*2 (J.P.M.L. December 18, 2001) (choosing the District of Minnesota, in which only two cases out of 36 then pending cases were venued, because “centralization in this district permits the Panel to effect the Section 1407 assignment to a major metropolitan court that i) is centrally located, ii) is not currently overtaxed with other multidistrict dockets, and iii) possesses the necessary resources, facilities, and technology to sure-handedly devote the substantial time and effort to pretrial matters that this complex docket is likely to require.”)

As previously noted, the Northern District of Ohio has experience managing pharmaceutical and medical device products liability MDL litigations, and has the resources and administrative experience for handling such matters efficiently. Further, the Northern District of Ohio has a proven track record for efficiency in processing civil cases: the median time from filing a complaint to disposition during the 12-month period ended December 31, 2006 was 13.1 months, while the median time from filing to trial was 19.5 months. *See Defendants' Exhibit 2, U.S. District Courts – Median Time Intervals from Filing to Disposition of Civil Cases, in Statistical Tables for the Federal Judiciary 2006*, available at <http://www.uscourts.gov/stats/dec06/C05Dec06.pdf>. The Northern District compares favorably with the 28.5 month median time from filing to trial in the Southern District of Ohio and is very similar to the 12.3 month median time from filing to disposition in the Southern District (especially considering that the Northern District had more than twice as many pending cases in that period: 5,722 cases in the Northern District to 2,223 in the Southern District). The Northern District of Ohio can efficiently manage this litigation.

**C. The Northern District of Ohio is Both Easily Accessible and Geographically Central to the Parties.**

In reviewing the venues of the cases filed thus far, there is no district which emerges as the “center of gravity” for this litigation. Cases have been filed in federal courts in Arkansas, California, Colorado, Georgia, Illinois, Kansas, Louisiana, Minnesota, Missouri, Ohio, South Carolina, Tennessee, Texas and Wisconsin. The Bayer Defendants submit that consideration should be given to finding a transferee district which is geographically central to the parties and which is metropolitan and easily accessible. The Northern District of Ohio is the central district which should be the transferee district for these cases.

The Panel often considers the geographic centrality of the cases when selecting a transferee court. In the Prempro products liability litigation, the Panel did not choose the district where the majority of actions were then pending, but instead chose the Eastern District of Arkansas, where one case was pending and which was geographically central to the parties and had the resources the complex litigation would need. In re Prempro Products Liability Litig., 254 F. Supp. 2d 1366 (J.P.M.L. 2003); *see also* In re ORTHO EVRA Products Liability Litig., 422 F. Supp. 2d 1379 (J.P.M.L. 2006) (ordering transfer to the Northern District of Ohio in part because of its central geographic location); In re Metoprolol Succinate Patent Litig., 329 F. Supp. 2d 1368, 1370 (J.P.M.L. 2004) (ordering transfer to the Eastern District of Missouri because it was the “location of the first-filed action and pretrial proceedings are already well under way” and “this accessible metropolitan district is well equipped with the resources that this complex docket is likely to require”); In re Educational Testing Service PLT 7-12 Test Scoring Litig., 350 F. Supp. 2d 1363, 1365 (J.P.M.L. 2004) (ordering transfer to the Eastern District of Louisiana, which “provides an accessible, metropolitan location with favorable caseload conditions.”); In re Inter-Op Hip Prosthesis Products Liability Litig., 149 F. Supp. 2d 931, 933

(J.P.M.L. 2001) (ordering transfer to the Northern District of Ohio, in part, because it "is an accessible, geographically central metropolitan district").

The Northern District of Ohio is geographically central to the parties in the GBCA cases filed thus far. Moreover, Judge Polster sits in Cleveland, which is a major metropolitan city with an international airport with direct flights to many cities across the country, and with hotel accommodations that are readily available and affordable.

## **II. The Southern District of Ohio Is A Less Suitable Forum For This Litigation**

Plaintiffs contend in their motion that the Southern District of Ohio is the best transferee forum for these cases, but they do not offer much in support of their chosen district beyond an *ex parte* communication with the judge about a possible MDL and their contention that the five cases there are allegedly more advanced than the four cases in the Northern District of Ohio or other cases around the country. However, the Southern District of Ohio cases have barely commenced discovery and are not as advanced as the Plaintiffs would like the Panel to believe. For example, the Plaintiffs have not served any discovery on the Bayer Defendants in the only Southern District of Ohio case in which they are defendants (*Frazier*) and no discovery plan or scheduling order has been entered in that case. Also, as previously discussed, the Southern District of Ohio is somewhat less efficient than the Northern District in handling cases from filing to disposition. For these reasons, the Southern District of Ohio is a less suitable forum for the GBCA MDL than the Northern District of Ohio.

CONCLUSION

For the foregoing reasons, Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer HealthCare LLC, Bayer Corporation, and Bayer Pharmaceuticals Corporation respectfully request that if plaintiffs' motion for transfer and consolidation pursuant to 28 U.S.C. §1407 is granted, that this litigation be transferred to the Northern District of Ohio.

Dated: December 6, 2007

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CH/ 28222.1

EXHIBIT 1  
to

RESPONSE OF DEFENDANTS BAYER HEALTHCARE PHARMACEUTICALS INC.,  
BAYER HEALTHCARE LLC, BAYER CORPORATION AND  
BAYER PHARMACEUTICALS CORPORATION TO PLAINTIFFS' MOTION FOR  
TRANSFER AND CONSOLIDATION PURSUANT TO 28 U.S.C. § 1407

James G. Carr  
Chief Judge

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November 6, 2007

Honorable John G. Heyburn II, Chairman  
Judicial Panel on Multidistrict Litigation  
Thurgood Marshall Federal Judiciary Building  
One Columbus Circle, NE  
Room G-255, North Lobby  
Washington, DC 20002-8004

Re.: In re. Gadolinium Contract Dyes Products Liability Litigation  
MDL 1909

Dear John:

I am informed by one of my Toledo colleagues, Judge Jack Zouhary, that a few days ago he held a case management conference in James Babione v. General Electric Co., No. 3:07 CV 1977 (N.D. Ohio, W.D.). Jack also tells me that his conference occurred shortly after he had received your letter of October 26th regarding a pending Motion to Transfer these cases pursuant to 28 U.S.C. § 1407.

I understand that Jack has discussed the issue of possible transfer to our District with the counsel in his case. They agree that it would make good sense to have this case proceed as an MDL action in Ohio.

The Judges of our District have developed considerable experience with MDL litigation. A Cleveland colleague, Judge Dan Polster, has also already met with counsel on one of these cases. His case management skills are excellent, and he is willing to take on this assignment.

I recommend our District generally and Dan in particular for your consideration.

With best regards,

  
James G. Carr  
Chief Judge

cc: Hon. Jack Zouhary  
Hon. Dan Polster  
Barry Hill, Esq.  
David List, Esq.  
J. Philip Calabrese, Esq. ✓  
Jeffery Luthi, Clerk of the Panel

J. PHILIP CALABRESE  
NOV 14 2007

EXHIBIT 2  
to

RESPONSE OF DEFENDANTS BAYER HEALTHCARE PHARMACEUTICALS INC.,  
BAYER HEALTHCARE LLC, BAYER CORPORATION AND  
BAYER PHARMACEUTICALS CORPORATION TO PLAINTIFFS' MOTION FOR  
TRANSFER AND CONSOLIDATION PURSUANT TO 28 U.S.C. § 1407

Table C-5. (December 31, 2006—Continued)

Circuit and District	Total Cases		No Court Action		Court Action				Median Time Interval In Months	
	Number of Cases	Median Time Interval In Months	Number of Cases	Median Time Interval In Months	Before Pretrial		During or After Pretrial			
					Number of Cases	Median Time Interval In Months	Number of Cases	Median Time Interval In Months		
5TH	21,201	8.4	4,883	6.5	13,440	8.8	2,350	13.2	428	
LA,E	3,264	9.7	121	2.9	1,751	5.8	1,323	15.6	69	
LA,M	759	11.9	208	5.0	516	11.9	25	24.5	10	
LA,W	1,555	12.9	502	9.3	981	12.4	33	21.4	39	
MS,N	901	12.6	192	5.3	570	12.1	113	17.4	26	
MS,S	3,631	6.5	1,696	6.3	1,953	6.9	39	22.0	43	
TX,N	2,845	7.6	146	6.3	2,639	7.6	3	-	57	
TX,E	1,734	10.5	350	5.8	1,289	10.1	44	12.7	41	
TX,S	4,162	8.6	1,158	5.0	2,160	7.6	752	10.7	92	
TX,W	2,350	9.3	610	7.3	1,671	10.8	18	16.0	51	
6TH	18,844	10.3	3,692	5.1	11,175	11.5	3,695	12.1	282	
KY,E	1,742	10.3	217	5.6	1,490	10.1	21	21.0	14	
KY,W	1,230	8.6	213	8.7	891	7.8	112	18.4	14	
MI,E	3,892	9.5	750	4.4	1,326	6.5	1,755	11.0	61	
MI,W	865	8.3	136	3.5	705	8.9	10	19.0	14	
OH,N	5,722	13.1	877	5.2	3,869	19.9	828	10.0	48	
OH,S	2,223	12.3	894	8.0	817	12.9	472	14.1	40	
TN,E	1,114	12.9	152	5.0	476	9.6	455	15.0	31	
TN,M	1,154	10.5	100	3.9	1,012	11.4	13	16.0	29	
TN,W	902	12.4	353	9.7	489	12.6	29	24.0	31	
7TH	12,784	7.9	3,926	5.1	7,268	8.3	1,357	12.2	232	
IL,N	6,418	6.5	2,321	5.3	3,519	6.3	478	12.0	100	
IL,C	706	9.1	302	9.0	381	9.5	10	22.0	13	
IL,S	809	8.9	222	6.4	547	8.1	18	16.2	22	
IN,N	1,273	9.7	308	6.8	664	9.4	279	16.6	22	
IN,S	2,084	10.5	548	7.2	1,196	10.0	293	13.6	27	
WI,E	1,063	8.7	172	4.0	774	8.5	84	15.8	33	
WI,W	451	4.7	53	2.0	188	3.6	195	5.5	15	
8TH	15,250	12.0	4,054	5.1	6,065	9.1	4,867	37.0	264	
AR,E	1,416	13.1	292	12.7	1,061	13.6	10	14.0	53	
AR,W	731	11.4	53	9.0	626	11.7	28	1.0	24	
IA,N	470	10.0	60	5.8	387	9.2	4	-	19	
IA,S	606	11.9	101	9.3	340	8.9	145	16.3	20	
MN	7,032	31.9	1,722	3.6	668	5.1	4,809	37.3	33	
MO,E	2,039	7.7	736	7.0	1,255	7.0	3	-	45	
MO,W	1,792	8.1	871	6.3	879	9.0	19	19.5	23	
NE	717	8.3	36	1.0	614	8.5	35	17.0	32	
ND	201	11.2	72	6.0	112	12.7	4	-	13	
SD	246	10.4	111	10.4	123	9.5	10	19.0	2	